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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,554	THRAMANN, JEFFREY J.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology (line 2, "comprises"). Correction is required. See MPEP § 608.01(b).

2. In line 94 of the specification, reference number 108 has been defined to be a bypass "stent graft". Line 98 refers to reference number 108 as a bypass "catheter". Change "catheter" in line 98 to --stent graft--. In line 140 of the specification, reference number 404 has been defined to be a "seating surface". Line 141 refers to reference number 404 as a "proximate end". Change "proximate end" in line 141 to --seating surface--. Line 179 contains a grammatical error. Change "from" to --form--. In lines 198-199, the access port is referred to as reference number "712". The access port has been defined as reference number "512". Change "712" in line 199 to --512--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the vessel" in lines 3 and 9. Claim 16 recites the limitations "the wall" and "the main vessel" in line 10. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,3, and 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans et al. (Patent No. 5,709,713).

Regarding claim 1, Evans et al. disclose a main vessel stent graft (Figure 16, element 52) inherently capable of extending in a vessel until it is proximate a portion of a vascular anatomy to be bypassed, and a bypass stent graft (56) comprising a proximate end (not labeled) and a distal end (not labeled). Figure 16 shows the proximate end of the bypass stent graft (56) is received in an access port (55) on a wall

of the main vessel stent graft (52) in a sealing relationship. The bypass stent graft (56) is flexible (column 2, lines 12-15) and although it is "usually" shorter, it could be constructed with any desired length (column 10, lines 47-50). Therefore, the bypass stent graft (56) is inherently capable of being bent back towards the vessel in order to be positioned in a sealing relationship with the vessel such that the bypass stent graft (56) bypasses a portion of the vascular anatomy. In the alternative, it would have been obvious to bend the bypass stent graft (56) back towards the vessel to be positioned in a sealing relationship with the main vessel in order to bypass a portion of the vascular anatomy. Regarding claim 3, Evans et al. disclose an access port (Figure 15, element 55) defined by an edge (inner ring portion of port 55 between the outer and inner surface of the stent graft 52) and comprising a seating surface (inner surface of stent graft 52 about the edge of port 55). Figure 16 shows the proximate end of the bypass stent graft (56) comprises an engaging surface (outer surface of stent graft 56 that is inserted in port 55) such that when the bypass stent graft (56) is received in the access port (55), the seating surface and the engaging surface form a seal that inhibits blood flow. Regarding claim 6, Evans et al. disclose at least the proximate end of the bypass stent graft (56) comprises a shaped memory alloy (column 2, lines 24-29), and Figure 16 shows the sealing relationship between the engaging surface and the seating surface after activation. Regarding claim 7, Figure 16 shows the proximate end (portion inserted in access port 55) of the bypass stent graft (56) resides in a first vessel (1L1) and the distal end of the bypass stent graft resides in a second vessel (1L2).

6. Claims 10, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (Patent No. 5,653,743).

Regarding claim 10, Figure 1 shows a main vessel stent graft (1) and at least one branch connecting stent graft (8). Figure 1 further shows the at least one branch connecting stent graft (8) is received in an access port (7) on a wall of the main vessel stent graft (1) forming a sealing relationship. Figure 4 shows the distal end of the branch connecting stent graft (8) resides in a branch vessel. Regarding claim 12, Figure 1 shows an access port (7) defined by an edge (9), and a seating surface (inner portion about edge 9 that is located between the outer and inner surface of the main vessel stent graft 1). The proximate end of the branch connecting stent graft (8) comprises an engaging surface (the outside surface of the proximate end), and Figure 1 shows a sealing relationship between the engaging surface of the branch connecting stent graft (8) and the access port (7). Regarding claim 13, Figure 5 shows that at least one branch connecting stent graft (8) comprises a plurality of branch connecting stent grafts.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Shmulewitz (Patent No. 5,961,548).

Evans et al. disclose a vascular stent graft as described in claim 1, but do not disclose puncturing the wall of the main vessel stent graft to establish the access port (55). Shmulewitz teaches puncturing the wall of the main vessel stent graft (perforations; Figure 3A, element 31) in order to join a second section in a separate step of the implantation process (column 2, lines 26-29). This method enhances the ease with which the legs of the graft may be deployed in the branches of a bifurcated body lumen (column 2, lines 13-16). It is obvious the punctures would have to be expanded in a controlled pattern in order to provide an access port for the bypass stent graft. Therefore, to puncture the wall of the main vessel stent graft of Evans et al. and expand the puncture in a controlled pattern would have been obvious to one of ordinary skill in the art at the time the invention was made in order to ease the process of deploying the stent grafts.

9. Claims 4-5, 9, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Venbrux (Patent No. 5,443,497).

Regarding claims 4-5, Evans et al. disclose a vascular stent graft as described in claim 1, but do not disclose a material between the seating surface and the engaging surface. Venbrux teaches any adhesive material can be used (column 3, lines 51-53)

between a seating surface (underside of flared ends 36 and 38) and an engaging surface (outside of tubular members 20 and 28) in order to ensure a robust connection. Therefore, to construct the bypass stent graft of Evans et al. with any adhesive material between the seating and engaging surface would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a durable connection between the bypass stent graft and the main vessel stent graft. Regarding claim 9, Evans et al. do not teach the proximate end of the bypass stent graft is flared. Venbrux teaches the proximate end of the stent graft is flared in order to seal the puncture in the lumen when the device is installed to bypass a blockage or to create communication between an artery and a vein (column 3, lines 35-41). Therefore, to construct the proximate end of the bypass stent graft of Evans et al. flared would have been obvious to one of ordinary skill in the art the time invention was made in order to provide a seal between stent grafts.

It is noted that applicant is invoking 112 6th paragraph. Regarding claims 19-20, Evans et al. disclose a vascular stent graft comprising a first stent graft (Figure 1, element 52) with a port (55) in a wall, and a second stent graft (Figure 16, element 56) being received in the port (55) in the wall. Evans et al. do not disclose the means for coupling the first stent graft and the second stent graft in a sealing relationship about the port. Venbrux teaches any adhesive material can be used (column 3, lines 51-53) between a seating surface (underside of flared ends 36 and 38) and an engaging surface (outside of tubular members 20 and 28) in order to ensure a robust connection. Therefore, to construct the vascular stent graft of Evans et al. with a means for coupling

the first stent graft and the second stent graft in a sealing relationship would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a durable connection between the first stent graft and second stent graft.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Martin.

Evans et al. disclose a vascular stent graft as described in claim 1, but do not disclose a branch connecting stent. Martin teaches a branch connecting stent graft (Figure 1, element 8) coupling a main vessel stent graft (Figure 5, element 1) and a bypass stent graft (18), so that other arteries and vessels are not covered or bypassed (column 1, lines 23-33) during stenting. Figure 5 shows the branch connecting stent graft (8) couples the main vessel stent graft (1) and the bypass stent graft (18) in a sealing relationship. Therefore, to construct the vascular stent graft of Evans et al. with a branch connecting stent graft would have been obvious to one of ordinary skill in the art at the time the invention was made in order to maintain blood flow through all arteries and vessels when stenting a system.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Shmulewitz.

Martin discloses a vascular stent graft as described in claim 10, but does not disclose puncturing the wall of the main vessel stent graft to establish an access port. Shmulewitz teaches puncturing the wall of the main vessel stent graft (perforations; Figure 3A, element 31) in order to join a second section in a separate step of the implantation process (column 2, lines 26-29). This method enhances the ease with

which the legs of the graft may be deployed in the branches of a bifurcated body lumen (column 2, lines 13-16). It is obvious the punctures would have to be expanded in a controlled pattern in order to provide an access port for the bypass stent graft. Therefore, to puncture the wall of the main vessel stent graft of Martin and expand the puncture in a controlled pattern would have been obvious to one of ordinary skill in the art at the time the invention was made in order to ease the process of deploying the stent grafts.

12. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Dereume et al. (Patent No. 5,639,278).

Regarding claim 14, Martin discloses a vascular stent graft as described in claim 10, but does not disclose that it is expandable. Dereume et al. disclose a stent graft comprising an expandable material (column 1, lines 18-26), so that it is of a size and shape suitable for insertion into the desired body passageway (column 2, lines 61-64) when unexpanded. Figure 22 shows the sealing relationship once the graft is expanded. Therefore, to construct at least the proximate end of the branch connecting stent graft of Martin with an expandable material would have been obvious to one of ordinary skill in the art at the time the invention was made in order to insert the branch connecting stent graft into the desired passageway.

Regarding claim 16, Martin discloses a main vessel stent graft (Figure 1, element 1) and at least one branch connecting stent graft (8). Figure 4 shows the at least one branch stent graft (8) comprises a distal end (not labeled) and a proximate end (not labeled); the proximate end resides about a wall of the main vessel stent graft

(1). It would have been obvious to include at least one radiopaque marker on the proximate end of the branch connecting stent graft (8) such as the ones on the main stent graft (platinum wire; Figure 1, elements 12 and 11) in order to allow its location to be tracked (column 3, lines 8-21). A wall of the main vessel stent graft is designed to form an access port (7) for each branch connecting stent graft (8) such that each of the access ports (7) are aligned with the proximate end; the alignment being identifiable by the at least one radiopaque marker (column 3, lines 8-21). Martin does not disclose a corresponding number of connecting stents. Dereume et al. teach connecting stents (Figure 26, element 121) in order to provide a branched device for use in the treatment and/or repair at branched vessel locations (column 3, lines 42-45). Figure 27 shows each of the connecting stents have a main vessel seating surface (125) and a branch vessel seating surface (124), such that the main vessel seating surface engages the wall of the main vessel stent graft (113) in a sealing relationship and the branch vessel seating surface engages a wall of the branch stent graft (109) in a sealing relationship (Figure 26). Therefore, to construct the vascular stent graft of Martin with connecting stents would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide treatment and/or repair at branched vessel locations.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Venbrux.

Martin discloses a vascular stent graft as described in claim 10, but does not

disclose the proximate end of the branch connecting stent graft is flared. Venbrux teaches the proximate end of the stent graft is flared in order to seal the puncture in the lumen when the device is installed to bypass a blockage or to create communication between an artery and a vein (column 3, lines 35-41). Therefore, to construct the proximate end of the branch connecting stent graft of Martin flared would have been obvious to one of ordinary skill in the art the time invention was made in order to provide a seal between stent grafts.

14. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Dereume as applied to claim 16 above, and further in view of Venbrux.

Regarding claim 17, Martin in view of Dereume disclose a vascular graft stent as described in claim 16, but does not disclose that the main vessel seating surface of the connecting stent is flared. Venbrux teaches the proximate end of the stent graft is flared in order to seal the puncture in the lumen when the device is installed to bypass a blockage or to create communication between an artery and a vein (column 3, lines 35-41). Therefore, to construct the seating surface of the connecting stent of Martin in view of Dereume flared would have been obvious to one of ordinary skill in the art the time invention was made in order to provide a seal between stent grafts. Regarding claim 18, Martin does not disclose that the branch vessel seating surface is expandable. Dereume teaches the branch vessel seating surface is expandable (column 1, lines 18-26) so that it is of a size and shape suitable for insertion into the desired body passageway (column 2, lines 61-64) in its unexpanded state. Figure 22 shows that the branch vessel seating surface (not labeled) is flush with the wall of the branch stent

graft(109). Therefore, to construct the branch vessel seating surface of Martin to be expandable would have been obvious to one of ordinary skill in the art at the time the invention was made in order to insert the branch connecting stent graft into the desired passageway.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 7:30 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Tyson MT
April 24, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/28/06.